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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
12/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/855,320	BAYER, ROBERT	
	Examiner	Art Unit	
	GANAPATHIRAMA RAGHU	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *107-112,115,117,119 and 120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *107-112,115,117,119 and 120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application Status

In response to the Office Action mailed on 08/13/09, applicants' response filed on 11/04/09 is acknowledged, said response amended claims 107-110, 115, 117, 119 and 120. Claims 107-112, 115, 117, 119 and 120 are pending in this application and are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn-Claim Rejections: 35 USC § 112

Previous rejection of claims 107-112, 115, 117, 119 and 120 rejected under 35 U.S.C. 112, first paragraph, for enablement and written-description is being withdrawn due to claim amendments.

Maintained-Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 107-112, 115, 117, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe JB[1] (U.S. Patent No.: 5,324,663, date of patent 06/28/94) or Lowe[2] et al., (U.S. Patent No.: 5,770,420, date of patent 06/23/98) or Lowe JB[3] (U.S. Patent No.: 6,268,193, date of patent 07/31/01) or Sasaki et al., (U.S. Patent No.: 7,094,530, date of patent 08/22/06, claiming priority to US Application No.: 08/361,306 filed on 11/29/1994) and in view of de Vries et al., (J. Biol. chem., 1995, Vol. 270 (15): 8712-8722, in IDS), Seed B., (WO 96/40881, in IDS), Staudacher E., (Trends Glycosci and Glycobiol., 1996, Vol. 8 (44): 391-408), in IDS), Malissard et al., (Biochem Biophys

Res Commun., 2000, Vol. 267: 169-173, in IDS) and Prieels et al., (J. Biol. Chem., Vol. 256 (20): 10456-10463, in IDS).

Claims 107-112, 115, 117, 119 and 120 are directed to any method of modifying the fucosylation pattern of a recombinant glycopeptide comprising any acceptor moiety, said method comprising contacting said recombinant glycopeptide with a reaction mixture comprising a fucose donor moiety and any recombinant **human** FucT-VI or FucT-VII fucosyltransferase of **undefined structure** including variants and mutants and wherein said recombinant FucT-VI or FucT-VII provides at least 2-, 4- or 8-fold greater fucosylation of said glycopeptides than is achieved under identical conditions using any recombinant **human** FucT-VI or FucT-VII fucosyltransferase of **undefined structure** including variants and mutants.

Lowe JB[1] or Lowe[2] et al., or Lowe JB[3] disclose an isolated polypeptide annotated as FucT-VI and lacking a membrane anchoring domain and to a method for modifying the fucosylation pattern of a recombinant polypeptide and highly purified polypeptide (entire documents).

Specifically, Lowe JB[1] (U.S. Patent No.: 5,324,663) disclose an isolated polypeptide (SEQ ID NO: 14) annotated as FucT-VI having and lacking a membrane anchoring domain and a method for modifying the fucosylation pattern of a recombinant polypeptide as claimed (entire document; especially column 2, lines 25-35; donor moieties, columns 8-10; use of said glycosyltransferase in enzymatic reactions to produce glycoproteins, glycolipids, oligosaccharides or polysaccharides of interest, column 13; recombinantly produced glycosyltransferase and abundant quantities of

purified glycosyltransferase and use of said enzyme in solutions or solid matrix as bioreactors capable of enzymatic synthesis of glycoproteins column 16, lines 5-11; especially fucosyltransferase lacking membrane anchoring domain, columns 19-20; mechanisms for producing purified enzyme by the use of antibody affinity columns or fusion proteins comprising *Staph. aureus* protein A, columns 26-27 and column 46; Example VI cloning, expression of SEQ ID NO: 14 including polypeptide lacking the membrane anchoring domain, purification of expressed enzyme to high purity using affinity columns and fucosyltransferase assays, columns 87-92).

Said reference further teaches both *in vitro* and *in vivo* fucosylation of glycoproteins of interest as indicated by the title of the document " Methods and products for the synthesis of oligosaccharide structures on glycoproteins, glycolipids, or as free molecules.... furthermore, applicants are directed to the following sections of 5,324,663 document.

Column 2: lines 56-60 discloses; "It is another object of this invention to provide these unmodified and modified isolated genes and cDNAs, and to use them, for example in modifying cell surface oligosaccharide structure via gene transfer approaches or via in vitro glycosylation reactions."

Column 8: lines 15-68 discloses; fucosyltransferases, another type of glycosyltransferases are provided by the present invention, are associated with the following linkages: (1) .... Including the linkages (Galβ1, 4GlcNAc-OR or NeuAcα2, 3Galβ1, 4GlcNAc-OR, wherein R is an amino acid, a saccharide, an oligosaccharide or an aglycon group).

Column 10: lines 45-61 discloses; "In another embodiment...The enzyme of the invention transforms the precursor into desired oligosaccharide, polysaccharide, glycolipid, or glycoprotein which is thereby obtained".

Column 13: lines 43-45 discloses; "in another embodiment…These enzymes can be used in bioreactors in *in vitro*, large scale, synthesis of oligosaccharides or glycolipids or for glycosidic modification of proteins and glycoproteins".

Column 16: lines 30-33 discloses; "enzymatic catalysis is extraordinarily efficient; virtually complete conversion of substrate to product can be achieved. By contrast, chemical synthesis of these structures is a multi-step process; yields at each step may be much less than 100%..."

Specifically, Lowe[2] et al., (U.S. Patent No.: 5,770,420) disclose an isolated polypeptide (SEQ ID NO: 14) annotated as FucT-VI and lacking a membrane anchoring domain and a method for modifying the fucosylation pattern of a recombinant polypeptide as claimed (entire document; especially column 2, lines 25-35; donor moieties, columns 10-12; use of said glycosyltransferase in enzymatic reactions to produce glycoproteins, glycolipids, oligosaccharides or polysaccharides of interest, column 14; recombinantly produced glycosyltransferase and abundant quantities of purified glycosyltransferase and use of said enzyme in solutions or solid matrix as bioreactors capable of enzymatic synthesis of glycoproteins column 13; especially fucosyltransferase lacking membrane anchoring domain, column 21; Example VI cloning, expression of SEQ ID NO: 14 including polypeptide lacking the membrane anchoring domain, purification of expressed enzyme to high purity using affinity columns

and fucosyltransferase assays, mechanisms for producing purified enzyme by the use of antibody affinity columns or fusion proteins comprising *Staph. aureus* protein A, columns 87-93).

Said reference further teaches both *in vitro* and *in vivo* fucosylation of glycoproteins of interest as indicated by the title of the document " Methods and products for the synthesis of oligosaccharide structures on glycoproteins, glycolipids, or as free molecules…. furthermore, applicants are directed to the following sections of 5,770,420 document.

Column 2: lines 46-50 discloses; "It is another object of this invention to provide these unmodified and modified isolated genes and cDNAs, and to use them, for example in modifying cell surface oligosaccharide structure via gene transfer approaches or via in vitro glycosylation reactions."

Columns 9-10: lines 1-68 discloses; fucosyltransferases, another type of glycosyltransferases are provided by the present invention, are associated with the following linkages: (1) …. Including the linkages (Galβ1, 4GlcNAc-OR or NeuAcα2, 3Galβ1, 4GlcNAc-OR, wherein R is an amino acid, a saccharide, an oligosaccharide or an aglycon group).

Columns 13-14: lines 65-68 of column 13 and lines 1-10 of column 14 discloses; "in another embodiment…These enzymes can be used in bioreactors in *in vitro*, large scale, synthesis of oligosaccharides or glycolipids or for glycosidic modification of proteins and glycoproteins".

Column 15: lines 33-35 discloses; “in another embodiment…These enzymes can be used in bioreactors in *in vitro*, large scale, synthesis of oligosaccharides or glycolipids or for glycosidic modification of proteins and glycoproteins”.

Column 18: lines 32-36 discloses; “enzymatic catalysis is extraordinarily efficient; virtually complete conversion of substrate to product can be achieved. By contrast, chemical synthesis of these structures is a multi-step process; yields at each step may be much less than 100%...".

Similarly, Sasaki et al., disclose an isolated polypeptide annotated as FucT-VII and lacking a membrane anchoring domain and to a method for modifying the fucosylation pattern of a recombinant polypeptide and highly purified polypeptide (entire document).

Specifically Lowe JB[3] disclose an isolated polypeptide (SEQ ID NO: 14) annotated as FucT-VI having and lacking a membrane anchoring domain and a method for modifying the fucosylation pattern of a recombinant polypeptide as claimed (entire document; especially column 2, lines 25-35; donor moieties, columns 8-10; use of said glycosyltransferase in enzymatic reactions to produce glycoproteins, glycolipids, oligosaccharides or polysaccharides of interest, column 13; recombinantly produced glycosyltransferase and abundant quantities of purified glycosyltransferase and use of said enzyme in solutions or solid matrix as bioreactors capable of enzymatic synthesis of glycoproteins columns 13-15; especially fucosyltransferase lacking membrane anchoring domain, column 19; Example VI cloning, expression of SEQ ID NO: 14 including polypeptide lacking the membrane anchoring domain, purification of

expressed enzyme to high purity using affinity columns and fucosyltransferase assays, mechanisms for producing purified enzyme by the use of antibody affinity columns or fusion proteins comprising *Staph. aureus* protein A, columns 83-90; recombinantly purified fucosyltransferase isolated with grater than 95%-98% purity with very high specific activity; claims 1-10, columns 123-124).

Specifically, Sasaki et al., (U.S. Patent No.: 7,094,530) disclose an isolated polypeptide (SEQ ID NO: 2) and lacking a membrane anchoring domain and a method for modifying the fucosylation pattern of a recombinant polypeptide as claimed (entire document; especially column 9, lines 15-40; fucosyltransferase lacking membrane anchoring domain, column 27, lines 1-16, columns 45-46; column 34, lines 27-49; activity assays, columns 35-36; industrial applicability, column 54; claims, columns 73-74).

Said reference further teaches; Column 9: lines 8-25 discloses; “Alpha-1, 3-fucosyltransferase produced in accordance with the present invention can be purified using ordinary methods of purifying glycosyltransferases… or purify the same by affinity chromatography”.

Column 9: lines 31-40 discloses; “Carbohydrate chains can be synthesized *in vitro* using Alpha-1, 3-fucosyltransferase of the present invention. For example, GlcNAC in lactosamine structure (Galβ1-4GlcNAc structure) in glycoproteins, glycolipids or oligosaccharides can be provided with α1$\rightarrow$3 linkage".

Column 74: Claim 14 directed to an *in vitro* method of glycosylation.

de Vries et al., (J. Biol. chem., 1995, Vol. 270 (15): 8712-8722, in IDS) teach that structure acceptor specificities and enzyme kinetics for different recombinant fucosyltransferases inherently varies (column 2, page 8712); Table I (page 8713) and the kinetics also varies for any given fucosyltransferase such as soluble and truncated forms (page 8718, column 1).

Seed B., (WO 96/40881, in IDS), teach extensive structural and functional diversity among fucosyltransferases including recombinantly produced fucosyltransferases (page 2).

Staudacher E., (Trends Glycosci. and Glycobiol., 1996, Vol. 8 (44): 391-408), in IDS), teach vast differences in biochemical properties among cloned human fucosyltransferases (Table III, page 393).

Malissard et al., (Biochem Biophys Res Commun., 2000, Vol. 267: 169-173, in IDS) teach that even among cloned and recombinantly produced fucosyltransferase, depending upon the cellular context in which the recombinant fucosyltransferase was produced, the autoglycosylation patterns of the enzyme vary and said patterns determine the activity of the enzyme.

Prieels et al., (J. Biol. Chem., Vol. 256 (20): 10456-10463, in IDS) also demonstrate the naturally derived fucosyltransferases purified by biochemical means have potential contaminants due to co-purification and the activity of said contaminant varies (entire document).

Therefore, it would have been obvious to a person of ordinary skill in the art to combine the above teachings to select and employ an highly purified recombinant fucosyltransferase such as FuCT-VI or FucT-VII with desired kinetic properties in the fucosylation reaction, as said combination teaches fucosyltransferases differ in their kinetic properties and furthermore source of the enzyme governs the biochemical property of said fucosyltransferases; for example recombinant *vs*. fucosyltransferase purified by biochemical means and differences in the activity profile of fucosyltransferases obtained from different sources.

However, said references are silent regarding the concentration of said recombinant FucT-VI or FucT-VII fucosyltransferase is at least 1 Unit/ml (as in claim 108) or wherein said full-length recombinant glycopeptide is a clotting factor or Factor VIII or Factor IX (as in claims 111 and 112) or at least about 2mg/ml (as in claims 119 and 120).

It would have been obvious to a person of ordinary skill in the art to combine the above teachings to reconstitute the expressed polypeptides in a buffer system to any required concentration such as 50mU or at least 2mg/ml for the assay of the enzymatic activity of FucT-VI or FucT-VII fucosyltransferase enzymes and the use of said enzymes in method for modifying the fucosylation pattern of any recombinant polypeptide such as clotting factor or Factor VIII or Factor IX. Said references teach the isolation and purification of FucT-VI or FucT-VII fucosyltransferase enzymes, said purity in the range of 95%-98%, the protein concentration of said enzymes such as ug/ul, enzyme assays, methods for glycosylation of products of interest and determining the efficiency of

glycosylation by said enzymes in said glycosylated products. Therefore a skilled artisan based on the knowledge and information provided in said teachings will certainly be able to determine the specific concentration i.e., Units/ml of said purified enzymes necessary for successfully fucosylating any recombinant polypeptide such as clotting factor or Factor VIII or Factor IX (modify the fucosylation pattern) and to reconstitute the purified enzymes in a suitable buffer to the requisite amount of activity. Motivation to combine the teachings derives from the fact that FucT-VI or FucT-VII fucosyltransferase enzymes are employed in industrial applications for their ability to synthesize various sugar molecules and modification of proteins or sugars by their ability to transfer sugar moieties on acceptor sites of peptide or sugar chain acceptors and furthermore said enzymes when provided with known activity information such as Units/ml will be useful for immediate use and applications without the additional step of determining the specific activity of said enzymes.

The expectation of success is high, because, the disclosure of Lowe JB[1] or Lowe[2] et al., or Lowe JB[4] teach an isolated polypeptide annotated as FucT-VI and lacking a membrane anchoring domain, methods for modifying the fucosylation pattern of any recombinant polypeptide and highly purified polypeptide (entire documents) and similarly, Sasaki et al., disclose an isolated polypeptide annotated as FucT-VII and methods for modifying the fucosylation pattern of a recombinant polypeptide and highly purified polypeptide (entire document) and the teachings of de Vries et al., Seed B., Staudacher E., Malissard et al., and Prieels et al., provide guidance for selecting the appropriate fucosyltransferase depending on the experimental need.

Therefore, the above reference renders claims 107-112, 115, 117, 119 and 120 *prima facie* obvious to one of ordinary skill in the art.

Applicants have traversed the above rejection with the following arguments:

(1) "The alleged *prima facie* obviousness is deficient because the cited references alone, or in any combination, fail to teach each and every element found in the claims. In, particular, the combination of references fail to teach a method that requires transfer of fucose by isolated, recombinantly produced human FucT-VI or FucT-VII to a recombinant polypeptide…wherein the fucosyltransferase provides at least 2-fold greater fucosylation of the glycopeptides than is achieved under identical conditions using isolated FucT-V" **(pages 8-9 of applicants' response dated 11/04/09)**.

(2) "Prior to the instant application one of skill in the art would not have had a reasonable expectation of success in practicing the invention in which human FucT-VI or FucT-VII provides at least 2-fold greater fucosylation of said glycopeptides than is achieved under identical conditions using recombinant, isolated FucT-V. This is surprising and unexpected" **(page 9 of applicants' response dated 11/04/09)**.

Reply (1) & (2): Applicant's arguments filed on **11/04/09** have been fully considered but they are not persuasive. Examiner takes the position cited references are in congruence with the obviousness rejection and teach all limitations of the instant claims and expectation of success.

Examiner would like to reiterate, the cited prior art provides ample guidance with respect to all the elements of the instant invention i.e., the disclosure of Lowe JB[1] or Lowe[2] et al., or Lowe JB[4] teach an isolated polypeptide annotated as FucT-VI and lacking a membrane anchoring domain, methods for modifying the fucosylation pattern of any recombinant polypeptide and highly purified polypeptide (entire documents) and similarly, Sasaki et al., disclose an isolated polypeptide annotated as FucT-VII and methods for modifying the fucosylation pattern of a recombinant polypeptide and highly purified polypeptide (entire document) and the teachings of de Vries et al., Seed B., Staudacher E., Malissard et al., and Prieels et al., provide guidance for selecting the appropriate fucosyltransferase depending on the experimental need; structural and functional differences, kinetic properties, substrate diversity, reaction conditions, recombinantly produced enzymes, differences in activities depending on the source of the enzyme.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Therefore, contrary to applicants' arguments, examiner continues to hold the position and is supported in the following eaxminer's arguments:

i) The instant invention is a simple combination of elements taught in the prior art, wherein the elements of prior art are combined to yield predictable results and the choice is from a finite number of identified elements with a highly predictable outcome and expectation of success.

ii) The cited references are in congruence with the obviousness rejection and teach all limitations of the instant claims i. e., meet all the criteria and parameters (Teaching, Suggestion and Motivation) as defined by *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and the rationale for TSM test (Teaching, Suggestion and Motivation) according to KSR ruling.

iii) Obviousness does not require an absolute certainty of success but merely a reasonable expectation thereof, so long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art and this is sufficient to establish a *prima facie* case of obviousness.

iv) Moreover, the objectives of the cited references need not be the same as the instant invention to be used in an Obviousness rejection. So long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art. This is sufficient to establish a *prima facie* case of obviousness (MPEP. 2144 [R-6]).

Furthermore, in fact all the elements in the instant invention have been simply assembled from the findings of preexisting art. Contrary to applicants' arguments, the combination has provided the logical progression and understanding of the key elements in the discipline of fucosylation of glycopeptides were well known in the art

and the cited references provide all the necessary pieces one would need to apply this basic strategy to determine the fucosylation pattern and kinetics of the reaction.

The basis for the examniner to continue to hold his position is reasoned below; examiner has provided unequivocal evidence for combining the cited references and that the cited references have been properly applied in this obviousness rejection in accordance with the factual enquires set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and the rationale for TSM test (Teaching, Suggestion and Motivation) according to KSR ruling. Furthermore the cited references teach all the limitations of the instant claims.

The cited references render claims 107-112, 115, 117, 119 and 120 *prima facie* obvious to one of ordinary skill in the art when one applies the Teaching, Suggestion and Motivation (TSM) test under the rationale for arriving at a conclusion of obviousness as suggested by the KSR ruling. The rationale applied for this rejection is as follows:

(1) Combining prior art elements according to known method to yield predictable results.

(2) Simple substitution of one known element for another to obtain predictable results.

(3) "Obvious to try"- choosing from a finite number of identified, predictable solution, with a reasonable expectation of success.

The examiner has provided the rationale to support a conclusion that the claims would have been obvious in that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known

methods **with no change in their respective functions**, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at 398 (2007), 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

Claims 107-112, 115, 117, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe JB[1] (U.S. Patent No.: 5,324,663, date of patent 06/28/94) or Lowe[2] et al., (U.S. Patent No.: 5,770,420, date of patent 06/23/98) or Lowe JB[3] (U.S. Patent No.: 6,268,193, date of patent 07/31/01) or Sasaki et al., (U.S. Patent No.: 7,094,530, date of patent 08/22/06, claiming priority to US Application No.: 08/361,306 filed on 11/29/1994) and in view of de Vries et al., (J. Biol. chem., 1995, Vol. 270 (15): 8712-8722, in IDS), Seed B., (WO 96/40881, in IDS), Staudacher E., (Trends Glycosci and Glycobiol., 1996, Vol. 8 (44): 391-408), in IDS), Malissard et al., (Biochem Biophys Res Commun., 2000, Vol. 267: 169-173, in IDS) and Prieels et al., (J. Biol. Chem., Vol. 256 (20): 10456-10463, in IDS).

Allowable Subject Matter/Conclusion

None of the claims are allowable. Claims 107-112, 115, 117, 119 and 120 are rejected for the reasons identified in the Rejections and Summary sections of this Office

Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652